

WE CLAIM:

Asd 110-139

1. A composite bone graft, comprising: a plurality of bone portions layered to form a graft unit, and one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.
2. A composite bone graft comprising:
two or more distinct bone portions, and
one or more biocompatible connectors, wherein said biocompatible connectors hold together said two or more bone portions to form said composite bone graft, said biocompatible connectors do not comprise an adhesive.
3. A composite bone graft comprising two or more connected, distinct, bone portions, said connected, distinct, bone portions do not comprise an adhesive.
4. A composite bone graft comprising three or more connected, distinct, bone portions, said connected, distinct, bone portions are not connected with an adhesive.
5. The composite bone graft of any one of claims 1 or 2, said bone portions are selected from the group consisting of: cortical bone and cancellous bone.
6. A composite bone graft, comprising:
a first bone portion;
a second bone portion;
a third bone portion, said first, second and third bone portions are layered to form a graft unit; and
one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

- ✓ 7. A composite bone graft, comprising:
- a first cortical bone portion;
- a second cortical bone portion;
- a cancellous bone portion disposed between said first cortical bone portion and said second cortical bone portion to form a graft unit; and
- one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.
- ✓ 8. A composite bone graft, comprising:
- a first cortical bone portion;
- a second cortical bone portion provided on said first cortical bone to form a graft unit; and
- one or more biocompatible connectors, connecting said graft unit, said biocompatible connectors do not comprise an adhesive.
- ✓ 9. A composite bone graft, comprising:
- a first bone portion;
- a second bone portion provided on said first bone portion to form a graft unit; and
- one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.
10. A composite bone graft, comprising: a plurality of cortical bone portions layered to form a graft unit, and one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

11.

A composite bone graft, comprising:

one or more cortical bone portions layered to form a first unit;

one or more cortical bone portions layered to form a second unit;

one or more cancellous bone portions layered to form a third unit; said third unit disposed between said first unit and said second unit to form a graft unit; and

one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

12. The composite bone graft of any one of claims 1, 2, or 11, said biocompatible connectors comprising one or more mechanical biocompatible connectors.

13. The composite bone graft of any one of claims 1, 2, or 11, said biocompatible connectors comprising a chemical biocompatible connector, said chemical biocompatible connector does not comprise an adhesive.

✓ 14. The composite bone graft of claim 12, said mechanical biocompatible connectors comprise one or more pins.

15. The composite bone graft of claim 12, wherein said mechanical biocompatible connectors comprise one or more biocompatible materials selected from the group consisting of: cortical bone; stainless steel; titanium; cobalt-chromium-molybdenum alloy; a plastic of one or more members selected from the group consisting of: nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone; and one or more bioabsorbable polymers.

16. The composite bone graft of any one of claims 1-4, 6-9, or 10, said bone portions are configured to provide an interlocking fit between adjacent bone portions.

17. The composite bone graft of claim 15, said one or more bioabsorbable polymers selected from the group consisting of: poly(galactic acid), poly(lactic acid) and copolymers thereof.
18. The composite bone graft of claim 15, said mechanical biocompatible connector further comprising one or more therapeutically beneficial agents.
19. The composite bone graft of claim 18, said therapeutically beneficial agents selected from the group consisting of: an osteoinductive substance, an anti-inflammatory agent, an antibiotic, a growth factor, and a chemotherapeutic substance.
20. The composite bone graft of claim 15, wherein said one or more mechanical biocompatible connectors comprise cortical bone.
21. The composite bone graft of claim 20, wherein cortical bone mechanical connectors comprises one or more cortical bone pins.
22. The composite bone graft of claim 14, wherein said one or more pins comprise one or more cortical bone pins.
23. The composite bone graft of any one of claims 14, 21, or 22, wherein said graft unit comprises one or more through-holes configured to accomodate said one or more pins.
24. The composite bone graft of claim 23, said through-holes are disposed perpendicular to interfaces of bone portions of said graft unit.
25. The composite bone graft of claim 24, wherein said one or more pins and said through-holes are configured to provide an interference fit for holding together said graft unit.

26. The composite bone graft of claim 25, wherein said one or more through-holes and said one or more pins are round and an inner diameter of a through-hole is smaller than a diameter of a pin, to provide an interference fit between said through-hole and said pin.
27. The composite bone graft of claim 21, said one or more cortical bone pins comprising a plurality of vertical grooves provided on a surface thereof.
28. The composite bone graft of claim 21, said one or more cortical bone pins comprising a roughened surface.
29. The composite bone graft of claim 21, said one or more cortical bone pins further comprising a slot extending from one end of said bone pin.
30. The composite bone graft of claim 22, said one or more cortical bone pins further comprising a slot extending from one end of said bone pin.
31. The composite bone graft of claim 23, wherein said one or more pins is threaded to provide a threaded engagement with said one or more through-holes.
32. The composite bone graft of claim 31, wherein said one or more pins is threaded and said one or more through-holes is threaded, to provide a threaded engagement between said one or more pins and said one or more through-holes.
33. The composite bone graft of claim 23, wherein said one or more pins and said one or more through-holes are configured to provide a slidable connection.
34. The composite bone graft of claim 23, wherein a cross-section of said one or more pins comprises a shape selected from the group consisting of: round, ovoid, square, rectangular, triangular, pentagon, hexagon, and trapezoidal.

35. The composite bone graft of any one of claims 1, 2, or 11, said composite bone graft comprising a member selected from the group consisting of: a parallelepiped; a parallel block; a square block; a trapezoid wedge; a cylinder; a tapered cylinder; a flattened curved wedge, and a polyhedron.
36. A composite bone graft, comprising:
a graft unit having one or more through-holes configured to accomodate one or more pins, said graft unit comprising:
two or more bone portions layered to form said graft unit, and
one or more pins connecting bone portions of said graft unit, said composite bone graft does not comprise an adhesive.
37. The composite bone graft of claim 36, said one or more pins comprising one or more biocompatible materials selected from the group consisting of: cortical bone; stainless steel; titanium; cobalt-chromium-molybdenum alloy; a plastic of one or more members selected from the group consisting of: nylon, polycarbonate, polypropylene, polyacetal, polyethylene, and polysulfone; and one or more bioabsorbable polymers.
38. The composite bone graft of claim 37, said two or more bone portions comprising:
a first bone portion comprising one or more cortical bone portions;
a second bone portion comprising one or more cortical bone portions; and
a third bone portion comprising one or more cancellous bone portions disposed between said first bone portion and said second bone portion to form said graft unit.

39. The composite bone graft of claim 38, said one or more pins comprise one or more cortical bone pins.
40. A composite bone graft, comprising:
a graft unit having one or more through-holes configured to accomadate one or more pins, said graft unit comprising:
a first plate-like cortical bone portion;
a second plate-like cortical bone portion;
a plate-like cancellous bone portion disposed between said first plate-like cortical bone portion and said second plate-like cortical bone portion
to form said graft unit, and
one or more cortical bone pins connecting bone portions of said graft unit, said composite bone graft does not comprise an adhesive.
41. A composite bone graft, comprising:
a graft unit having one or more through-holes configured to accomadate one or more pins, said graft unit comprising:
a first plate-like bone portion;
a second plate-like bone portion provided on said first plate-like bone to
form said graft unit, and
one or more bone pins for holding together said graft unit, said composite bone graft does not comprise an adhesive.

42. The composite bone graft of any one of claims 36, 40 or 41, said one or more through-holes are disposed perpendicular to interfaces of bone portions of said graft unit.
43. The composite bone graft of claim 42, wherein said one or more pins and said one or more through-holes are configured to provide an interference fit for holding together said graft unit.
44. The composite bone graft of claim 43, wherein said one or more through-holes and said one or more pins are round and an inner diameter of a through-hole is smaller than a diameter of a pin, to provide an interference fit between said through-hole and said pin.
45. The composite bone graft of claim 42, wherein said one or more pins and said one or more through-holes are configured to provide a slidable connection.
46. The composite bone graft of any one of claims 36, 40, or 41, said composite bone graft comprising a member selected from the group consisting of: a parallelepiped; a parallel block; a square block; a trapezoid wedge; a cylinder; a flattened curved block, a tapered cylinder; and a polyhedron.
47. The composite bone graft of claim 46, said composite bone graft is a polyhedron.
48. The composite bone graft of claim 46, said composite bone graft further comprising: one or more textured surfaces.
49. The composite bone graft of claim 48, said one or more textured surfaces comprising: a plurality of closely spaced continuous protrusions.

50. The composite bone graft of claim 49, wherein said continuous protrusions comprise a cross-section having one or more shapes selected from the group consisting of: irregular, triangular, square, rectangular, and curved.
51. The composite bone graft of claim 49, wherein said plurality of continuous protrusions are sized to be in a range of greater than or equal to 1.5 mm in length; 0.5 to about 10.0 mm in width and 0.1 to about 5.0 mm in depth.
52. The composite bone graft of claim 51, wherein said plurality of closely spaced continuous protrusions are spaced from about 0.0 to about 3.0 mm apart.
53. A method for restoring vertical support of the posterior column, comprising implanting a composite bone graft comprising two or more distinct bone portions held together by one or more biocompatible connectors, at a site in a patient.
54. The composite bone graft of claim 36, said composite bone graft comprising a flattened curved wedge having a centrally located through-hole disposed perpendicular to interfaces of bone portions of said graft unit.
55. A composite bone graft, comprising:
a graft unit having one or more through-holes configured to accomodate one or more pins, said graft unit comprising:
two or more bone portions layered to form said graft unit,
one or more pins connecting said bone portions of said graft unit, and
a centrally located through-hole disposed perpendicular to interfaces of layered bone portions of said graft unit, said composite bone graft does not comprise an adhesive.

56. A method for making a composite bone graft for implantation into a patient, comprising:
stacking two or more parallel bone planks to form a graft unit;
providing one or more through-holes in said graft unit perpendicular to interfaces of
bone planks;
connecting said two or more parallel bone planks of said graft unit with one or more
pins disposed in said one or more through-holes to form a pinned graft unit;
and
shaping said pinned graft unit to form said composite bone graft.
57. The composite bone graft of any one of claims 1, 2, 11, 36, 54, or 55, wherein said composite bone graft comprises one or more members selected from the group consisting of: human and animal bone.
58. The composite bone graft of any one of claims 1, 2, 11, 36, 54, or 55, wherein said composite bone graft is an allograft or xenograft.
59. The composite bone graft of any one of claims 1, 2, 11, 36, 54, or 55, wherein one or more of said bone portions comprise a demineralized bone portion.
60. The composite bone graft of claim 59, wherein said demineralized bone portion comprises a discontinuous demineralized bone portion.
61. The composite bone graft of claim 60, wherein said discontinuous demineralized bone portion comprises cancellous bone or cortical bone.
62. The composite bone graft of any one of claims 1, 2, 11, 36, 54, or 55, wherein one or more of said bone portions comprise a discontinuous bone portion.

63. The composite bone graft of claim 62, wherein said discontinuous bone portion comprises a demineralized discontinuous bone portion.
64. The composite bone graft of claim 63, wherein said demineralized discontinuous bone portion comprises cancellous or cortical bone.
65. The composite bone graft of claim 62, further comprising one or more therapeutically beneficial substances selected from the group consisting of: an osteoinductive material, an osteoconductive substance and a pharmaceutically active agent.
66. The composite bone graft of claim 65, said osteoconductive materials comprising one or more biocompatible matrix materials selected from the group consisting of: demineralized cortical bone, demineralized cancellous bone, discontinuous demineralized cortical bone, discontinuous cortical bone, collagen, cancellous bone, hydroxyapatite; polymeric matrix materials; bioglass; bioceramics; resorbable biomaterials; bioabsorbable polymers; a plastic matrix; stainless steel; titanium; and cobalt-chromium-molybdenum alloy matrix.
67. The composite bone graft of claim 65, said osteoinductive materials comprising one or more members selected from the group consisting of: autograft bone; allograft bone; demineralized cortical bone; demineralized cancellous bone; discontinuous demineralized cortical bone; collagen comprising one or more growth factors; collagen comprising demineralized bone; cancellous bone; cortical bone; and growth factors.

68. The composite bone graft of claim 65, said pharmaceutically active agent comprising one or more members selected from the group consisting of: a growth factor, a chemotherapeutic agent, an anti-inflammatory agent, and an antibiotic.
69. The composite bone graft of any one of claims 67 or 68, said growth factor comprising one or more members selected from the group consisting of: bone morphogenic protein, and transforming growth factor- β .
70. A composite bone graft, comprising:
one or more cortical bone portions layered to form a first unit;
one or more cortical bone portions layered to form a second unit;
one or more demineralized cancellous bone portions layered to form a third unit; said third unit disposed between said first unit and said second unit to form a graft unit; and
one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.
71. A composite bone graft, comprising:
one or more cortical bone portions layered to form a first unit;
one or more cortical bone portions layered to form a second unit;
one or more demineralized cortical bone portions layered to form a third unit; said third unit disposed between said first unit and said second unit to form a graft unit; and
one or more biocompatible connectors for holding together said graft unit, said biocompatible connectors do not comprise an adhesive.

72. The composite bone graft of claim 71, said one or more demineralized cortical bone portions comprising one or more discontinuous, demineralized cortical bone portions.
73. The composite bone graft of claim 70, said one or more demineralized cancellous bone portions comprising one or more perforated, demineralized cancellous bone portions
74. The composite bone graft of claim 72, said one or more discontinuous, demineralized cortical bone portions comprising one or more therapeutically beneficial agents.
75. The composite bone graft of claim 70, said one or more cancellous bone portions comprising one or more therapeutically beneficial agents.
76. A composite bone graft, comprising:
a first unit comprising one or more bone portions;
a second unit connected to said first unit, comprising one or more bone portions; and
one or more biocompatible connectors for connecting said first unit and said second unit, wherein said first unit and said second unit are not in physical contact and define a void therebetween, said biocompatible connectors do not comprise an adhesive.
77. The composite bone graft of claim 76, wherein said biocompatible connectors comprise one or more mechanical connectors.
78. The composite bone graft of claim 77, said one or more mechanical connectors comprising one or more cortical bone pins.

79. The composite bone graft of claim 76, further comprising one or more therapeutically beneficial substances disposed in said void and located between and in physical contact with said first unit and said second unit.
80. The composite bone graft of claim 79, said therapeutically beneficial substances comprising one or more members selected from the group consisting of: osteoinductive materials; osteoconductive materials; and pharmaceutically active agents.
81. The composite bone graft of claim 80, said osteoconductive materials comprising one or more biocompatible matrix materials selected from the group consisting of: demineralized cortical bone, demineralized cancellous bone, discontinuous demineralized cortical bone, discontinuous cortical bone, collagen, cancellous bone, hydroxyapatite; polymeric matrix materials; bioglass; bioceramics; resorbable Biomaterials; bioabsorbable polymers; a plastic matrix; stainless steel; titanium; and cobalt-chromium-molybdenum alloy matrix.
82. The composite bone graft of claim 80, said osteoinductive materials comprising one or more members selected from the group consisting of: autograft bone; allograft bone; demineralized cortical bone; demineralized cancellous bone; discontinuous demineralized cortical bone; collagen comprising one or more growth factors; collagen comprising demineralized bone; cancellous bone; cortical bone; and growth factors.

83. The composite bone graft of claim 80, said pharmaceutically active agent comprising one or more members selected from the group consisting of: a growth factor, a chemotherapeutic agent, an anti-inflammatory agent, and an antibiotic.
84. The composite bone graft of any one of claims 82 or 83, said growth factor comprising one or more members selected from the group consisting of: bone morphogenic protein, and transforming growth factor- β .
85. The composite bone graft of claim 80, comprising said one or more osteoinductive substances and one or more osteoconductive substances, wherein said one or more osteoinductive substances are disposed within a matrix of said one or more osteoconductive substances.
86. The composite bone graft of any one of claims 2 or 3, said bone portions comprising two or more cortical bone portions layered to form a graft unit.
87. The composite bone graft of claim 86, said cortical bone portions comprising complementary patterns provided thereon to enable an interlocking fit between adjacent cortical bone portions.
88. The composite bone graft of claim 86, further comprising: one or more channels selected from the group consisting of: a vertically disposed channel, a horizontally disposed channel, and a randomly disposed channel.
89. The composite bone graft of claim 88, said one or more channels further comprising: one or more therapeutically beneficial substances.
90. A composite bone graft, comprising: two or more distinct interlocking cortical bone portions.

91. The composite bone graft of claim 90, said two or more distinct interlocking bone portions are each provided with complementary discrete or continuous interlocking patterns.
- ✓ 92. A composite bone graft, comprising: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other.
- ✓ 93. A composite bone graft, comprising: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other, and one or more locking pins partially or entirely traversing a dimension of said composite bone graft.
- ✓ 94. The composite bone graft of claim 93, wherein said dimension comprises length, width, or height.
- ✓ 95. A composite bone graft, comprising: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other to form an interlocked graft unit, said interlocked graft unit is self-locking.
- ✓ 96. A composite bone graft, comprising: two or more distinct adjacent bone portions, said distinct adjacent bone portions comprising complementary peg-like protrusions and corresponding depressions, said protrusions and depressions interlock to provide an interlocking fit between said adjacent bone portions.
97. The composite bone graft of claim 96, further comprising: one or more locking pins partially or entirely traversing a dimension of said composite bone graft.
98. The composite bone graft of anyone of claims 92, 93, 95, or 96, said two or more distinct adjacent bone portions comprise one or more members selected from the

- group consisting of: cortical bone and cancellous bone.
99. The composite bone graft of claim 98, said two or more distinct adjacent interlocking bone portions comprise cortical bone.
100. A composite bone graft, consisting essentially of: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other.
101. A composite bone graft, consisting essentially of: two or more distinct adjacent bone portions, said distinct adjacent bone portions comprising complementary peg-like protrusions and corresponding depressions, said protrusions and depressions interlock to provide an interlocking fit between said adjacent bone portions.
- ✓ 102. A composite bone graft, consisting essentially of: two or more distinct adjacent bone portions, said distinct adjacent bone portions comprising complementary peg-like protrusions and corresponding depressions, said protrusions and depressions interlock to provide an interlocking fit between said adjacent bone portions; and one or more locking pins partially or entirely traversing a dimension of said composite bone graft.
103. A composite bone graft, consisting essentially of: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other, and one or more locking pins partially or entirely traversing a dimension of said composite bone graft.
104. The method of claim 57, said two or more parallel bone planks comprising two or more parallel bone planks configured to interlock with each other.

105. The composite bone graft of claim 90, said two or more distinct interlocking bone portions are each provided with complementary discrete interlocking patterns.
106. The composite bone graft of claim 105, said discrete interlocking patterns comprising: peg-like protrusions provided on a bone portion and corresponding depressions provided on an adjacent bone portion, said protrusions and depressions interlock to provide an interlocking fit between said adjacent bone portions.
107. A composite bone graft, comprising: two or more distinct adjacent bone portions where adjacent bone portions are configured to interlock with each other to form an interlocked graft unit, and one or more locking pins traversing a dimension of said composite bone graft, to lock said interlocked graft unit.
108. A composite bone graft, comprising: two or more distinct interlocking bone portions, said interlocking bone portions are self-locking.
109. A composite bone graft, comprising: two or more distinct interlocking bone portions, and one or more locking pins to lock said interlocking bone portions.